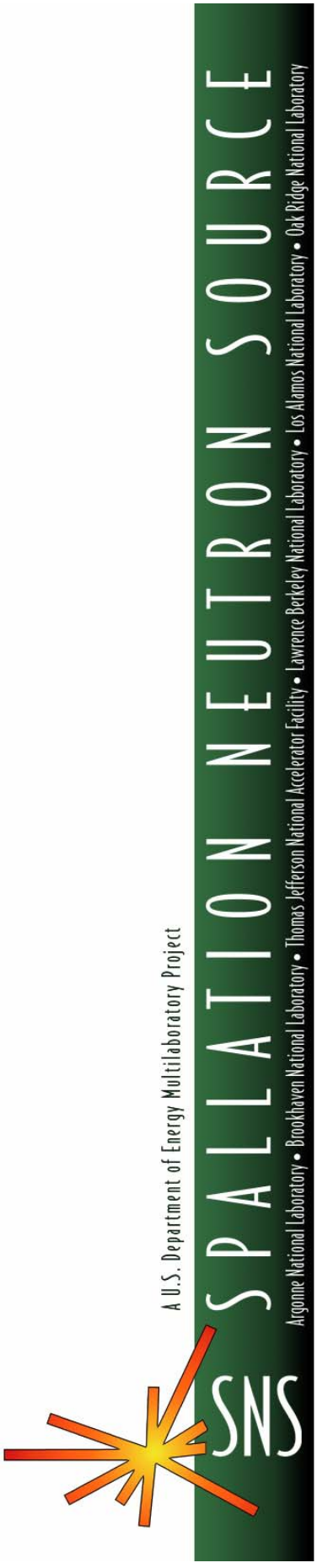
SNS-QA-P01 Revision 4
(SNS 102040000-QA0001-R04)

Spallation Neutron Source Quality Manual

May 2006



SPALLATION NEUTRON SOURCE QUALITY MANUAL

SNS-QA-P01-R04
APPROVALS

Date: May 2006

Supersedes SNS-QA-P01 Rev. 3, "Spallation Neutron Source Quality Assurance Plan," dated March 2004

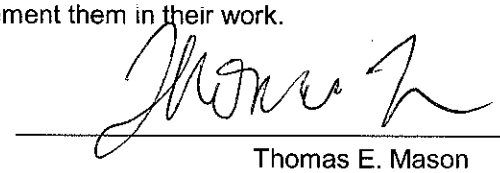
Copies: This document is available on the SNS web site,
http://www.sns.gov/projectinfo/qa/qa_home.html
If you are working with a copy, you should periodically verify that you have the current version.

SNS QUALITY POLICY

The quality policy of the SNS is to meet or exceed the expectations of the SNS users and the DOE, and to protect the health and safety of everyone while continually improving the facility and service to users.

The primary objective of the SNS QA program is to implement the quality assurance criteria in DOE o 414.1C (ref. 1) in a way that achieves adequate protection of the workers, the public, and the environment, taking into account the work to be performed and the associated hazards, and using the ISO 9001-2000 standard as required. SNS creates and updates additional objectives to help achieve its goals. The management approach described in this manual is the means chosen for simultaneously achieving all the objectives.

All SNS personnel are required to familiarize themselves with the SNS quality policy, manual and procedures, and to implement them in their work.



Thomas E. Mason
ORNL Associate Laboratory Director

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REVISION LOG

QUALITY MANUAL (QM)

REVISION	DATE	QM Pages	BY	DESCRIPTION
4	05/24/2006	ALL	JWM	Complete rewrite to quality manual replacing project QA plan

PART I GENERAL

1. PURPOSE

The purpose of the Spallation Neutron Source (SNS) Directorate is to build and operate the latest-generation short-pulse spallation neutron source as a user facility to meet the needs for scientific understanding and technological innovations.

This document is a revision of the quality assurance plan for the SNS, to cover the period where the construction project is being completed and post-construction operation begins. It describes the quality management system (QMS) of the SNS, and the title has been changed to “Quality Manual” instead of “Quality Assurance Plan,” to be consistent with the language of the ISO 9001-2000 standard. It has been developed by applying the quality assurance criteria specified in ref.1. It discusses how the criteria are satisfied, using a graded approach. As required by ref. 1, this QA plan also integrates quality requirements from ORNL’s integrated management system (ref. 13) and was developed using parts of the applicable consensus standard, ISO 9001-2000 (ref. 8).

The project is controlled by management systems described in the SNS Project Execution Plan (PEP, ref.10), followed after project completion by the Operations Execution Plan (OEP, ref. 11). The primary objective of the SNS QA program, as mandated by the PEP/OEP, is to implement the quality assurance criteria in O 414.1C (ref. 1) in a way that achieves adequate protection of the workers, the public, and the environment, taking into account the work to be performed and the associated hazards. Further, while SNS as an accelerator facility is excluded from 10CFR830 (refs. 6 and 7), it is designed and constructed substantially in accordance with those requirements.

Note that regardless of the performer of the work, the ORNL M&O contractor is responsible for complying with the requirements of the Contractor Requirements Document (CRD) in ref. 1.

2. SCOPE

This plan provides requirements applicable to all activities conducted by or for the SNS Directorate, including the neutron instruments and the experiments conducted at SNS, and to all activities performed by or for the SNS Project until its completion, from research and development (R&D) through facility acceptance, operation, maintenance, and improvement.

Where beamline instruments or co-located facilities are governed by other QA plans or programs, the scope boundaries will be made clear in the plans or programs.

2.1 TRANSITION FROM CONSTRUCTION PROJECT TO OPERATING FACILITY

The Project Execution Plan (PEP) (ref.10) was established as the top management document for the SNS as a construction project. The SNS PEP served three basic functions. First, it described the management and project execution processes that had been approved by DOE management. In short, the PEP constituted the authorizing document for the “way of doing business” on the project. Second, the PEP established the project baselines (technical, schedule, and cost) against which project execution was measured. Changes to project execution were evaluated in terms of baseline impacts, and through graduated change control authority, appropriate levels of management became involved in decisions regarding project changes. Third, the PEP served as the primary reference document for all levels of the project team. Technical requirements, policies, and procedures for resource allocation, procurement, budgeting and finance, work authorization, management, reporting, reviews and evaluations, etc., all flowed down from the PEP.

Following SNS Project completion, the SNS Operations Execution Plan replaces the PEP as upper-

tier requirements document.

2.2 OTHER UPDATES AFFECTING THE SCOPE

The separate Target Systems QA Plan has been canceled because it was no longer needed after the target was clearly defined as under the scope of the accelerator safety order DOE 0 420.2B, not a nuclear facility with QA requirements under 10CFR830.

A quality plan tailored to the needs for SNS Instruments Next Generation (SING) is in place, (SNS SINGPRJ-20-QA0001). It is integrated into the SNS quality systems as described here.

The SNS Power Upgrade Project (PUP) will extend the capabilities of SNS and is covered by this QA Plan, which may be supplemented if needed by a project plan and additional procedures.

This plan is implemented by quality plans, procedures, and guides which are developed to accommodate specific quality requirements. Additional procedures and guides are accessible through the SNS QA Web Page at http://www.sns.gov/projectinfo/qa/qa_home.htm.

3. GRADED APPROACH

The SNS quality management system covers a variety of systems, components, and activities. Quality-assuring actions are applied commensurate with needs. Three grade levels (quality levels) are defined:

a) **Serious** potential consequences, requiring a **rigorous** series of actions.

b) **Important** potential impacts, *negative or positive*, justifying a **disciplined** set of actions.

c) **Routine** potential impacts, justifying **normal** actions.

Tables 1 and 2 explain the use of the grades. For any process, regardless of grade, improvement is expected using the plan-do-check-act cycle explained in section 4.5.

PLEASE NOTE: Consultation with an SNS quality assurance representative is expected whenever grade levels are being determined, because there are many factors to consider. For example,

(1) the relative importance to safety, safeguards, and security;
(2) the magnitude of any hazard involved;
(3) the life-cycle stage of a facility or item;
(4) the programmatic mission of a facility;
(5) the particular characteristics of a facility or item;
(6) the relative importance to radiological and non-radiological hazards, and
(7) any other relevant factors.

For software, it is also important to consider its use in the operation, creation or maintenance of credited engineered controls as described in the Safety Assessment Documents (refs. 10, 11).

Instructions: First determine the grade level in Table 1, then apply appropriate actions from Table 2. To determine the grade and subsequent actions for an item or activity, locate the appropriate risks on the matrix in Table 1. The most serious identified risk determines the grade. This table is repeated on form SNS-QA-F011, for use in recording a specific grading determination.

Table 1. Determination of Quality Level or Grade

Risk Type	Level 1. Serious Consequences	Level 2- Important Negatives	Level 2- Improvement	Level 3. Routine
Environ-ment Safety, and Health	Potential for (1) a death or total disability or severe adverse impact on the health or safety of a worker or the public, or (2) environmental damage that could exceed regulatory limits or involve significant cleanup costs, or (3) violating the Accelerator Safety Envelope, including such potential through affecting SNS credited engineered controls	Potential for injury or illness requiring hospitalization, temporary or partial disability, or moderately adverse impact on the environment or health or safety of a worker or the public, including such potential through affecting SNS credited engineered controls	Important potential for *reduced* injury or illness rates requiring hospitalization, temporary or partial disability, or *reducing* adverse impact on the environment or health or safety of a worker or the public, including such potential through affecting SNS credited engineered controls	Only minimal impact on the health and safety of the public or a worker, such as injury or illness requiring minor supportive treatment but not requiring hospitalization. Negligible impact on the environment
Compliance	Significant potential for noncompliance with state and federal laws and regulations or DOE requirements or an SNS Safety Assessment Document	Significant potential for noncompliance with ORNL or SNS procedures, or minor noncompliance with state and federal laws and regulations	Significant potential for *improving* compliance with ORNL or SNS procedures, or reducing minor noncompliances with state and federal laws and regulations	Only a potential for minor noncompliance with established management practices
User Impact	Potential for a significant adverse impact to an SNS user or an important impact to multiple users	Potential for important adverse impact to an SNS user but not affecting other users	Potential for important *positive* impact to an SNS user or benefitting multiple users	Only a potential for negligible impact to SNS users
Functional	Potential for a significant adverse impact to achieving or maintaining key performance and reliability goals of the SNS	Potential for important adverse impact to a major system or component, but not blocking SNS from key performance goals	Potential for important *positive* impact to a major system or component, or important to SNS achieving key performance goals	Only a potential for negligible impact to an SNS task, system, or component
Financial	Potential for unintended cost of five Full-Time Equivalent worker-years (FTE) or greater	Potential for unintended cost of 1/2 FTE or greater	Potential for *reducing* cost by 1/2 FTE or greater	Financial risk is less than 1/2 FTE
Public/Gov. Interest	Significant potential for loss of public or government confidence in SNS or its management	Some potential for reduced public or government confidence in SNS or its management	Important potential for *enhanced* public or government confidence in SNS or its management	Little or no potential for reduced public or government confidence

Table 2. Work Activities Chosen Based on Quality Levels (for software, use Table 3)

Level 1. Rigorous	Level 2. Disciplined	Level 3. Normal
Documented worker qualifications.[1,2]	Knowledgeable personnel employed, and compliance with ES&H requirements[1,2]	Knowledgeable personnel employed, and compliance with ES&H requirements[2]
Design reviews and *independent* verifications[1]	Design reviews and verifications[1]	Informal or no design reviews, verification
Thorough documentation (plans, drawings, specifications etc.)[1]	Adequate and appropriate documentation (plans, drawings, specifications etc.)[1]	Minimal documentation
Acceptance Checklist (ACL)[1]	ACL required[1]	ACL optional
Vendor qualification and surveillance[1]	Vendor qualification (questionnaire minimum)[1]	Little or no vendor qualification
Approved documented procedures[1]	Procedures as needed	Procedures other than safety may be informal
Complete oversight and assessment activities[1]	Oversight by general management assessments	Oversight performed by line supervision
Controlled measuring and test equipment (M&TE) [1]	Controlled M&TE[1]	M&TE generally not used
Formal inspection and testing[1]	Tests and inspections conducted appropriately[1]	Normal receipt inspection only, plus any ES&H requirements

[1]QA representative approvals are required.

[2]Only trained and qualified personnel may perform tasks unsupervised, that may affect safety and health

NOTE: Records are required to be put in the document control center for the actions listed as required for grades 1 and 2.

3.1 SOFTWARE QUALITY-ASSURING ACTIONS

For grades 1 and 2 , the software owner and their QA representative select and implement the applicable software quality assurance work activities from the following list to ensure that software performs its intended functions.

Table 3. Software Quality Assurance Actions

Software project management
Software risk management
Software configuration management
Procurement and vendor management
Software requirements identification and management
Software design and implementation
Software safety design
Verification and validation
Problem reporting and corrective action
Training of personnel in the design, development, use and evaluation of safety software

DOE G 414.1-4 (Ref. 10) provides acceptable implementation strategies for these SQA work activities.

4. GENERAL QUALITY REQUIREMENTS

SNS has established, documented, implemented, and now maintains a quality management system as described in this manual. SNS management has designated the SNS Operations Manager as the senior management position responsible for the development, implementation, assessment, and improvement of a QAP and QMS. These are actions important to DOE and ISO quality programs (refs. 1 and 8).

4.1 REQUIREMENT SOURCES

The program/system meets the following requirements.

(1) Implements QA criteria as defined in paragraph 3 of the CRD in ref. 1 and suspect/counterfeit items (S/CI) prevention requirements as defined in CRD paragraph 4 using a graded approach and describing how QA criteria and the graded approach are applied.

(2) In accordance with ref. 1, uses the appropriate voluntary national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used. The appropriate standard is ANSI/ISO/ASQ Q 9001-2000, *Quality Management System – Requirements* (for non-nuclear activities—*clearly applicable to SNS as a user facility).*

(3) Applies additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory).

(4) Integrates quality or management system requirements as defined in the CRD in ref. 1 with DOE directives and similar external requirements. Similar requirements include the following.

(a) DOE P 450.4, *Safety Management System Policy* (ref. 5);

(b) DOE P 450.5, Line Environment, Safety and Health Oversight (ref. 6);

NOTE: This integration requirement does not establish or imply a hierarchy of quality requirements or programs.

(c) Quality Guidance Usage. SNS must consider QA guidance in developing and implementing a QAP. DOE has provided refs. 2, 3 and 4 for this guidance.

4.2 ISO 9001:2000 USAGE

In accordance with commitment 6.1(2) above, SNS will continually improve its effectiveness in accordance with the requirements of the ISO 9001 Standard (ref. 8), and

a) identify the processes needed for the quality management system and their application throughout SNS,

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, and

e) monitor, measure and analyze these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

4.3 ISO 9001:2000 EXCLUSIONS

The SNS quality program is comprehensive and takes no exclusions of any part of the ISO 9001:2000 standard.

4.4 CREATING AND USING OBJECTIVES

The process for creating and updating objectives is a key feature of the SNS QMS. Prior to the periodic management review, progress on the current objectives is assessed, and relevant information and data are surveyed to determine if new objectives should be created for the next review period. Where objectives have been achieved or the work toward them has become routine, they may be removed from the current list. The management review includes consideration of these assessments and recommendations for altering the list of objectives. (See ref. 18 SNS Quality Objectives, 102040000-QA0041, R00 for the current list.)

Where the SNS quality objectives would be redundant to ORNL-managed performance evaluation or quality objectives for SNS, they will not be managed in duplicate but simply referred to in the SNS quality management review process.

4.5 PROCESS APPROACH TO WORK

The premise of the SNS Quality Management System is that all work can be seen as a process, as explained in ref. 8. The *plan-do-check-act* cycle allows for continual improvement of each process. These terms are explained as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the company's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives, and requirements for the product and report the results.

Act: take actions to continually improve process performance.

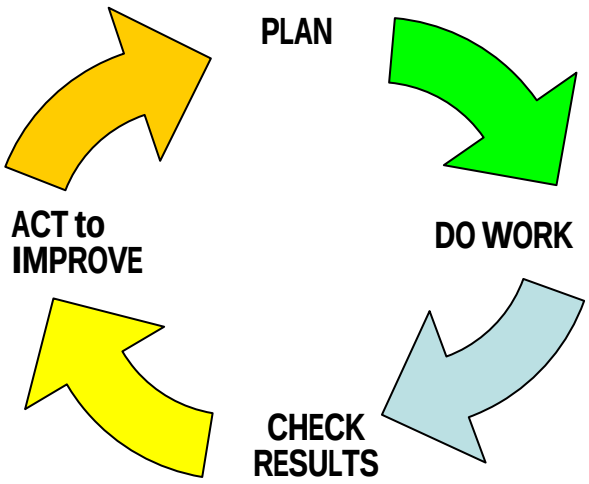

Figure 1. Plan-Do-Check-Act Cycle

4.6 MATURING OF PROCESSES

As processes are used and refined, they can begin to incorporate more reliable elements than when first introduced. As the probability of failures goes down, it has the effect of lowering the risk. Consequently the grade level of the process may move in the direction of normal. For example, when advancements in worker skills, tools, and materials make it possible for a job once done under special procedures to become “skill of the craft.” This is also referred to as a learning curve, because the processes typically take less time and effort as well.

4.7 DEFINITIONS

The following are definitions of terms used in this manual.

Acceptance Check List (ACL)—a document listing the criteria that will be checked to make sure an item or service is fit for use, with spaces to record and date the checks.

Corrective Actions—Actions taken to contain the effects of nonconformities, and to eliminate the nonconformities and their causes to prevent recurrence.

Credited Engineered Control (CEC) —a member of the set of defined engineered controls (e.g., interlocks and barriers) and administrative measures (e.g.,specific operator actions or training) taken to control or mitigate hazards from operations.” The CEC’s are given in references 11 and 12.

Nonconformance—(nonconformity) product or service which does not conform to requirements.

Quality—“Fitness of an item or design for its intended use.”

Quality Assurance (QA)—The set of actions taken to avoid known hazards to quality and to detect and correct poor results.

Quality Assurance Program (QAP)—The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work (ref. 1).

Quality Management System (QMS)—system to establish quality policy and objectives and to achieve those objectives. (ref. 8)

NOTE: A management system of an organization can include different management systems, such as a quality management system, a financial management system or an environmental management system.

Quality-assuring actions—Planning, analyses, documentation, and other actions necessary to comply with requirements and ensure that goals are achieved.

Preventive Actions—actions to eliminate the causes of potential nonconformities.

Safety—Environment, safety, and health (ES&H), including pollution prevention and waste minimization, as defined in SNS Environmental Safety and Health Plan (ref.8).

Safety Software—Software with specific functions in relation to nuclear facility structures, systems, or components (SSCs).

Software—Computer programs, operating systems, procedures, and associated documentation and data pertaining to the operation of a computer system.

Suspect/Counterfeit Items (S/CI)—A suspect item is one where there are indications it may not conform to specifications or standards, or may have been misrepresented by the supplier or manufacturer. A counterfeit item is a suspect item that has been copied or substituted without legal right or authority to do so or one whose material, performance, or characteristics are misrepresented by the supplier or manufacturer.

System Software—includes human-machine interface software, network interface software, and programmable logic controller (PLC) programming language software. System software also includes analysis and design software and management databases that are not part of a system but whose operation or malfunction can directly affect the system's function.

Traveler Check List—a document listing the steps that will be taken to prepare a particular item for use, with spaces to record and date the accomplishment of steps, which may be treated as an acceptance check list if it includes acceptance steps.

5. REFERENCES

5.1 DOE

1. O 414.1C, “Quality Assurance” (http://www.directives.doe.gov/pdfs/doe/doetext/neword/414/o4141c.pdf)
2. DOE G 414.1-1A “Management Assessment and Independent Assessment Guide” (http://www.directives.doe.gov/pdfs/doe/doetext/neword/414/g4141-1a.html)
3. DOE G 414.1-2A, “Quality Assurance Management Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance” (http://www.directives.doe.gov/pdfs/doe/doetext/neword/414/g4141-2a.pdf)
4. G 440.1-6 “Implementation Guide For Use With Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6C, Quality Assurance” (http://www.directives.doe.gov/pdfs/doe/doetext/neword/440/g4401-6.html)
5. G 414.1-3 “Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance” (http://www.directives.doe.gov/pdfs/doe/doetext/neword/414/g4141-3.pdf)
6. DOE O 420.B “Safety of Accelerator Facilities” http://www.directives.doe.gov/pdfs/doe/doetext/neword/420/o4202b.pdf
7. DOE P 450.4 “Safety Management System Policy” http://www.directives.doe.gov/pdfs/doe/doetext/neword/450/ p4504.html

5.2 CODE OF FEDERAL REGULATIONS, PART 10 (10 CFR)

8. 10 CFR 835, "Occupational Radiation Protection" (http://www.access.gpo.gov/nara/cfr/waisidx_00/10cfr835_00.html)

5.3 OTHER DOCUMENTS

9. ISO 9001:2000 “Quality Management Systems-Requirements”
10. ANSI/ISO/ASQ Q9000-2000 “Quality Management Systems,-Fundamentals and Vocabulary”
11. Spallation Neutron Source Final Safety Assessment Document for Proton Facilities (SNS 102030103-ES0018-R00)
12. Spallation Neutron Source Final Safety Assessment Document for Neutron Facilities (SNS 102030102-ES0016-R00)
13. ORNL Quality Assurance Program (http://sbms.ornl.gov/sbms/SBMSearch/ProgDesc/QAPD/NQAProgPD.cfm)

14. ORNL ISMS Program http://sbms.ornl.gov/sbms/SBMSearch/ProgDesc/lm003.cfm
15. Spallation Neutron Source Project Execution Plan, (SNS 102010100PN0001R03) (http://www-internal.sns.gov/dcrm/plans/SNS_PEP_App_C_R03.pdf)
16. SNS Environmental Safety and Health Plan (SNS 102030000-ES0001-R01) (http://www-internal.sns.gov/esh/safdoc/ES&H_Plan_Rev_1.pdf).
17. Configuration Management Plan (SNS-102010200-PC0002-R04) http://www-internal.sns.gov/dcrm/plans/SNS-102010200-PC0002-R03.pdf.
18. SNS Operations Execution Plan (SNS-110070000-PN0001-R00)
19. SNS Quality Objectives 102040000-QA0041, R00

5.4 SNS QUALITY PROCESSES/PROCEDURES

20. SNS-QA-P011, “Analysis Processes”
21. SNS-QA-P020, “Training and Qualification”
22. SNS-QA-P030, “Quality Improvement”
23. SNS-QA-P033, “Nonconformance Control”
24. SNS-QA-P034, “Suspect/Counterfeit Items”
25. SNS-QA-P031, “Corrective Action”
26. SNS-QA-P032, “Preventive Action”
27. SNS-QA-P040, “Documents and Records”
28. SNS-QA-P050, “Work Controls”
29. SNS-QA-P060, “Equipment Design Procedure”
30. SNS-QA-P061, “Software Design Procedure”
31. SNS-QA-P070, “Procurement”
32. SNS-QA-P080, “Inspection and Acceptance Testing”
33. SNS-QA-P090, “Management Assessment”
34. SNS-QA-P100, “Independent Assessment”

PART II QUALITY ASSURANCE CRITERIA

This Part is numbered according to the topics, or “criteria” of ref. 1.

1. MANAGEMENT/CRITERION 1—PROGRAM

SNS has an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work, and uses management processes, including planning, scheduling, and providing resources for work. They fall under the umbrella of the ORNL SBMS system, with important rules set forth in “Roles, Responsibilities, Accountabilities, & Authorities (R2A2s)” at http://sbms.ornl.gov/SBMS/R2A2s/R2A2main.cfm

The current official organization chart is maintained online at the ORNL website: http://www.ornl.gov/info/org_charts/sns_org.pdf

1.1 COMMUNICATIONS

The ORNL Associate Laboratory Director for SNS, together with division-level management, ensures that appropriate communication processes are established within the SNS organization and that communication takes place regarding the effectiveness of the quality management system. They also ensure that adequate infrastructure exists for communication, such as electronic distribution of management directives to employees, bulletin boards for announcements, and meetings where needed.

Group leaders and task leaders ensure workers are informed of expectations regarding quality, and that management is informed of quality issues when identified by the workers, as described in Section 5 of this Part.

Also as described in Section 5 of this Part, the SNS User Program management uses a website, electronic and other communications, and meetings with users to determine:

a) requirements specified by the users, including the requirements for pre-experiment, experiment performance and post-experiment activities,
b) requirements not stated by the users but necessary for specified or intended use, where known, and

user feedback, including complaints.

Design management ensures adequate communication across design interfaces, as described in Section 6 of this Part.

Procurement management ensures adequate communication of requirements to suppliers, as described in Section 7 of this Part.

1.2 REQUIREMENTS FOR THE QUALITY MANUAL

This manual includes information on:

a) the scope of the quality management system, including details of and justification for any exclusions,

b) the documented procedures established for the quality management system, or reference to them, and

d) a description of the interaction between the processes of the quality management system.

These features satisfy the requirements of ref. 8 for an ISO 9001-compliant quality manual.

This manual is coordinated with the Safety Assessment Documents (SAD's), which must include or reference a description of facility function, location, and management organization in addition to details of major facility components and their operation; (as required by refs 9 and 10).

(2) The SNS management system defines and implements management processes, including planning, scheduling, and providing resources for work. Key user-related processes are shown in Figure 3.

1.3 SEQUENCE AND INTERACTION OF PROCESSES

Figure 3 shows the sequence and interaction of processes directly affecting the user.

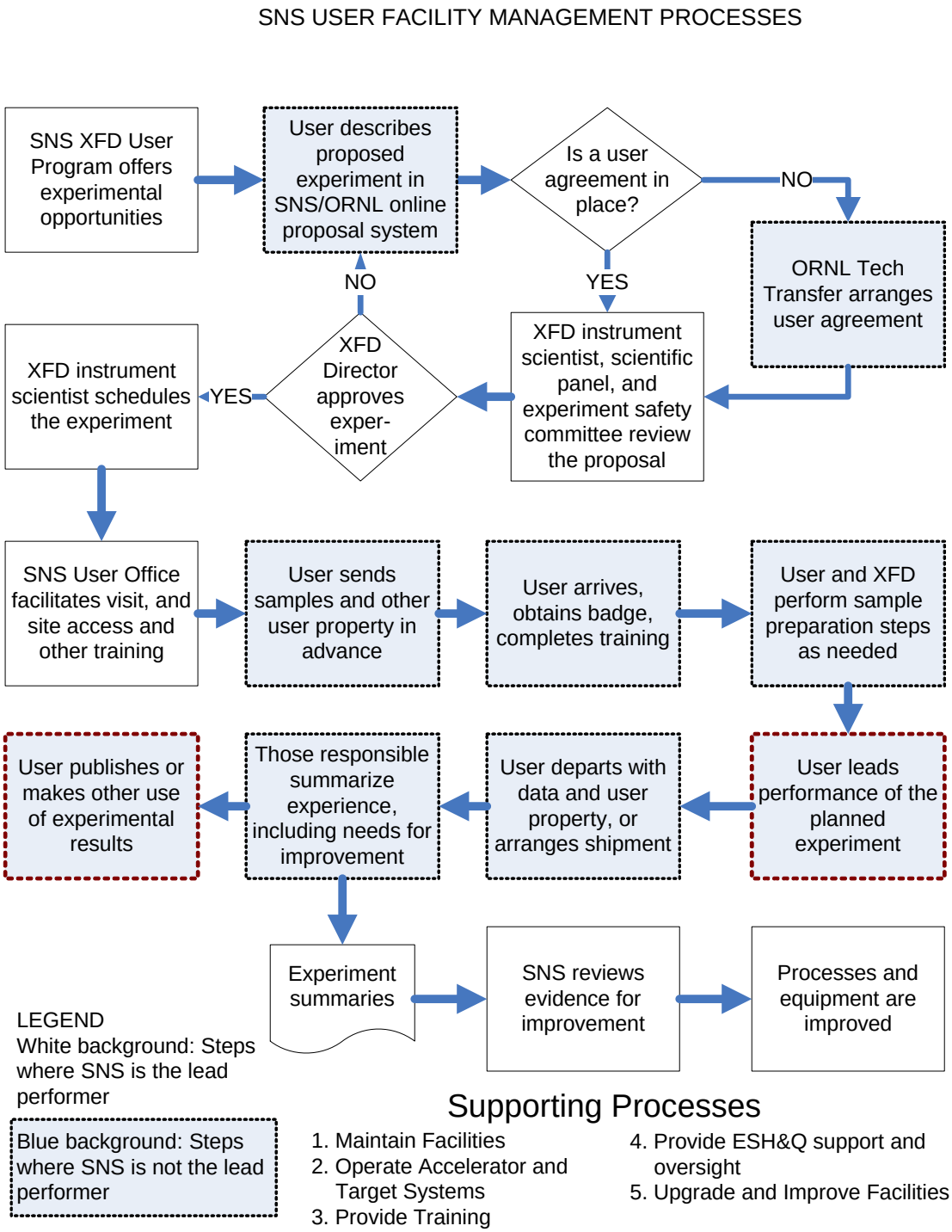

Figure 3. Sequence and Interaction of Processes Affecting Users

1.4 ANALYSIS

SNS performs analyses to support its management system and its products and services.

SNS plans and implements the monitoring, measurement, analysis and improvement processes needed:

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system. This includes determination of applicable methods, including statistical techniques, and the extent of their use.

The analysis of data provides information relating to

a) customer satisfaction,

b) conformity to product requirements

The processes listed in this section are described in SNS-QA-P011, “Analysis Processes.”

2. MANAGEMENT/CRITERION 2—PERSONNEL TRAINING AND QUALIFICATION.

The training and qualification process described in this section is implemented by procedure SNS-QA-P0, “Training and Qualification.”

SNS provides training and qualification programs consistent with those of ORNL, and meeting the following standards:

a) Personnel are trained and qualified to be capable of performing assigned work.

b) Continuing training is provided to personnel to maintain job proficiency.

c) Training and qualification requirements are established for each individual at the accelerator facility whose activities could affect safety and health conditions or whose safety and health could be affected by facility activities. Training and qualification is documented and kept current.

d) Only appropriately trained and qualified personnel, or trainees under the direct supervision of trained and qualified personnel, are permitted to perform tasks that may affect safety and health.

e) All personnel assigned to or using the accelerator facility (including emergency response personnel) are trained in the safety and health practices and emergency plans consistent with their involvement and the hazards present.

3. MANAGEMENT/CRITERION 3—QUALITY IMPROVEMENT

The quality improvement process described in this section is implemented by procedure SNS-QA-P030, “Quality Improvement.”

As one of the measurements of the performance of the quality management system, SNS monitors information relating to customer perception (both users and DOE) as to whether the organization has met customer requirements. The methods for obtaining and using this information are described in SNS-QA-P080.

SNS plans and implements the monitoring, measurement, analysis and improvement processes needed:

a) to demonstrate conformity of its products,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

Occurrence reporting will be as required by DOE and the ORNL SBMS for certain defined events or conditions.

3.1 CONTINUAL IMPROVEMENT

SNS continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. In particular, SNS

(1) Establishes and implements processes to detect and prevent quality problems.

(2) Identifies, controls and corrects items, services, and processes that do not meet established requirements.

(3) Identifies the causes of problems and includes prevention of recurrence as a part of corrective action planning.

(4) Reviews item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

3.2 UNREVIEWED SAFETY ISSUES

Activities that involve unreviewed safety issues must not be performed if significant safety consequences could result from either an accident or a malfunction of equipment that is important to safety and for which a safety analysis has not been performed. Activities involving identified unreviewed safety issues must not commence before DOE/NNSA has provided written approval.

3.3 NONCONFORMANCE CONTROL (CONTROL OF NONCONFORMING PRODUCT)

SNS ensures that its product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in procedure SNS-QA-P033, “Nonconformance Control.”

SNS deals with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, SNS takes action appropriate to the effects, or potential effects, of the nonconformity.

3.4 SUSPECT/COUNTERFEIT ITEMS (SCI) REQUIREMENTS

The suspect/counterfeit items controls described below are implemented by procedure SNS-QA-P034, “Suspect/Counterfiet Items.” It satisfies these requirements:

An S/CI prevention process must be developed and implemented as a part of the contractor’s QAP and must be commensurate with the facility/activity hazards and mission impact. The QAP

must be applied to identifying, analyzing, and removing S/CIs, and preventing them from being supplied to DOE/NNSA and its contractors. The QAP must address the following elements for S/CI prevention.

1. Preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls.
2. Training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs)
3. Identifying and disposing of S/CIs on site.
4. Restricting S/CI use to only those items that have been found acceptable through engineering analysis and formal disposition process.
5. Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources.

6. Identifying the management point of contact responsible for these activities to ensure that the DOE Office of Environment, Safety and Health has a viable recipient for S/CI information notices.

Work Process Controls: Work processes must be developed and implemented using available S/CI information, and must include the following elements.

1. Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment.
2. Procurement processes that prevent introduction of S/CIs by—
   (a) identifying technical and QA requirements in procurement specifications;
   (b) accepting only those items that comply with the procurement specifications consensus standards, and commonly accepted industry practices; and
   (c) inspecting inventory and storage areas to identify, control, and disposition S/CIs.
3. Inspection, identification, evaluation, and disposition of S/CIs installed in all Safety applications and other applications that create potential hazards. Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers.
4. Engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards. The evaluations must consider potential risks to the public and worker and cost/benefit impact, and include a schedule for replacement (if required).
5. Ensuring that S/CIs identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.
6. Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.
7. Testing procured or installed S/CIs as necessary using approved engineering test methods.
8. Reporting S/CIs to responsible DOE/NNSA line management offices; the Office of Environment, Safety and Health; and the IG. [DOE O 231.1A, *Environment, Safety, and Health Reporting*, dated 8-19-03, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse*, dated 3-22-01.]
9. Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention.

3.5 CORRECTIVE ACTIONS

SNS takes action to eliminate the cause of nonconformities in order to prevent recurrence, corrective actions are appropriate to the effects of the nonconformities encountered, and a documented procedure (SNS-QA-P031, “Corrective Action”) defines requirements for:

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,
e) records of the results of action taken, and
f) reviewing corrective action taken.

3.6 PREVENTIVE ACTIONS

SNS determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions will be appropriate to the effects of the potential problems.

A documented procedure (SNS-QA-P032, “Preventive Action”) defines requirements for:

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken, and
e) reviewing preventive action taken.

4. MANAGEMENT/CRITERION 4—DOCUMENTS AND RECORDS.

The documents and records processes described in this section are implemented by procedure SNS-QA-P040, “Documents and Records.” It gives directions to those who:

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
(2) Specify, prepare, review, approve, and maintain records.

4.1 CONTROL OF DOCUMENTS

Documents required by the quality management system are controlled.

Procedure SNS-QA-P040, “Documents and Records” has been established to define the controls needed:

a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they areretained for any purpose.

4.2 CONTROL OF RECORDS

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records are required to remain legible, and to be kept readily identifiable and retrievable. A documented procedure (SNS-QA-P040, “Documents and Records”) is used to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5. PERFORMANCE/CRITERION 5—WORK PROCESSES.

The process controls described in this section are implemented by procedure SNS-QA-P050, "Work Controls."

SNS requires that work be performed consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.

SNS line management at all levels provides acceptance standards when work is assigned. Work is assigned only to those capable of performing the work, because they are equipped with training and other resources needed.

The work control and configuration management programs work together to ensure that jobs are planned and approved based largely upon their importance to safety. Each individual task/system is screened and work planning and control are administered using a tailored approach. The work control process follows the principles of integrated safety management (ISM) of:

1) defining the work to be done and associated hazards;
2) developing and implementing appropriate hazard controls;
3) performance of the work within the controls; and
4) providing feedback on the work and striving to improve the process.

The work control process also ensures that individuals working on systems are properly trained to safely carry out the required work.

Work on CEC's requires a more rigorous routine than work on other components and systems. Work planning on this type of system will include involvement of operations, maintenance (including individuals directly involved in accomplishing the work), and engineering design, ensuring that safety functions and controls are recognized and maintained. Other disciplines are involved at the option of this core planning team based on the nature of the work. In addition, post maintenance testing is prescribed to confirm the proper operation of the serviced system/component.

Work control also involves the identification and control of potential hazards to both the worker and to the equipment being serviced. Work involving systems with significant hazard potential require special considerations including a more in-depth review and the identification of controls and work restrictions as needed.

5.1 WRITTEN PROCEDURES

Written procedures for conducting activities safely must be maintained; must be clear, current, and consistent with management systems and the configuration of the facility and equipment; and must be approved by the facility contractor's senior line management who are actively involved in the day-to-day operation of the facility.

Procedures must include descriptions of the tasks to be performed; safety and health precautions and controls; and requirements for initial conditions to be verified, operating conditions to be maintained, and data to be recorded, as applicable.

At a minimum, SNS is required to maintain procedures for—

(1) operation startup,
(2) normal operation,
(3) emergency conditions,
(4) conduct of maintenance,
(5) approval and conduct of experiments,
(6) review and approval of facility modifications,
(7) management of safety-related changes, and
(8) control of facility access.

5.2 PRESERVATION OF PRODUCT

SNS Maintains items to prevent damage, loss, or deterioration.

SNS will preserve the conformity of its products during internal processing and delivery to the intended destination. This preservation will include identification, handling, packaging, storage and protection. Preservation will also apply to the constituent parts of a product.

5.3 IDENTIFICATION AND CONTROL OF ITEMS

SNS identifies and controls items to ensure proper use. Important permanent equipment as well as calibrated measuring devices are tracked in a preventive maintenance and calibration database (Datastream).

5.4 CALIBRATION

SNS calibrates and maintains equipment used for process monitoring or data collection. Important components of the calibration program are the assignment of calibration coordinators within each group that uses measuring or process monitoring equipment, and a subcontractor providing on-site calibration for many of the electronic instruments. Datastream aids management of calibration status.

5.5 ACCELERATOR SAFETY ENVELOPE (ASE)

Any activity violating the ASE must be terminated immediately and the activity must not be restarted before the Department of Energy (DOE) has been notified and a revision to authorize the activity has been approved.

5.6 USER REQUESTS--CUSTOMER-RELATED PROCESSES

Section 1.3, Figure 3 illustrates the process for use of SNS by scientific users.

5.7 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

SNS will determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements related to the product, and
d) any additional requirements determined by SNS.

5.8 USER EXPERIMENT SUPPORT--REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT/SERVICE

SNS will review the requirements related to the product/service. This review will be conducted prior to SNS's commitment to supply a product to the user (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and will ensure that

a) product/service requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved, and
c) SNS has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review will be maintained.

Where the user provides no documented statement of requirement, the customer requirements will be confirmed by SNS before acceptance.

Where product/service requirements are changed, SNS will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, a formal review is impractical for each user arrangement. Instead the review can cover relevant information such as advertising material.

5.9 CUSTOMER PROPERTY

SNS will exercise care with customer property while it is under SNS's control or being used by SNS. SNS will identify, verify, protect and safeguard customer property. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this will be reported to the customer and records will be maintained.

NOTE Customer property can include intellectual property.

5.10 SOFTWARE QA

These requirements are necessary to ensure that safety software for SNS performs its intended specific functions in relation to structure, system, or component (SSC) and the classification, design, and analysis associated with SNS operations. Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers.

Work processes involving safety software must be developed and implemented using national or international consensus standards and must include the following elements.

a. Facility design authority involvement in identifying software specification, acquisition, design, development, verification and validation (including inspection and test), configuration management, maintenance, and retirement.

b. Identify, document, and maintain safety software inventory.

c. Use the grading levels that have been established for safety software, as documented in this quality manual.

d. Using the grading levels established and approved above, select and implement the applicable software QA work activities from the following list to ensure that safety software performs its intended functions. ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2000, must be used to implement these work activities. The standards used must be specified by the user and approved by DOE.

DOE G 414.1-4 provides acceptable implementation strategies and appropriate standards for these work activities.

(1) Software project management and quality planning
(2) Software risk management
(3) Software configuration management
(4) Procurement and supplier management
(5) Software requirements identification and management
(6) Software design and implementation
(7) Software safety
(8) Verification and validation
(9) Problem reporting and corrective action

(10) Training of personnel in the design, development, use, and evaluation of safety software

6. PERFORMANCE/CRITERION 6—DESIGN.

This section covers design of SNS structures, equipment, and software as well as design of items for users or other customers. The design process described in this section is implemented by procedure SNS-QA-P060, “Design and Development,” and additional procedures where needed for specialized areas of design work, such as electronics design, mechanical design with CAD models, design of software, etc.

6.1 DESIGN AND DEVELOPMENT PLANNING

SNS plans and controls the design and development of its products. These are the rules for planning SNS design work:

(1) Design items and processes using sound engineering/scientific principles and appropriate standards.

(2) Incorporate applicable requirements and design bases in design work and design changes.

(3) Identify and control design interfaces.

(4) Verify/validate the adequacy of design products through individuals or groups other than those who performed the work.

(5) Verify/validate work before approval and implementation of a design

6.2 ACCELERATOR SAFETY ENVELOPE (ASE)

A documented ASE must define the set of physical and administrative bounding conditions for safe operations, based on the safety analysis documented in the SAD.

During the design and development planning, SNS determines:

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

SNS manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

6.3 DESIGN INPUTS

Inputs relating to product requirements are determined and records are maintained. These inputs include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements must be complete, unambiguous and not in conflict with each other.

6.4 ALARA DESIGN

SNS works to maintain radiation exposure in controlled areas As Low as Reasonably Achievable (ALARA) through physical design features and administrative controls. The primary methods used are physical design features (e.g., confinement, ventilation, remote handling, and shielding).
Only for specific activities where use of physical design features is demonstrated to be impractical, are administrative controls used to maintain radiation exposures ALARA.

During the design of new facilities or modification of existing facilities, the following objectives are adopted:

i. Optimization methods shall be used to assure that occupational exposure is maintained ALARA in developing and justifying facility design and physical controls.
ii. The design objective for controlling personnel exposure from external sources of radiation in areas of continuous occupational occupancy (2000 hours per year) shall be to maintain exposure levels below an average of 0.5 mrem (5 microsieverts) per hour and as far below this average as is reasonably achievable. The design objectives for exposure rates for potential exposure to a radiological worker where occupancy differs from the above shall be ALARA and shall not exceed 20 percent of the applicable standards in §835.202 (ref. 7).
iii. Regarding the control of airborne radioactive material, the design objective shall be, under normal conditions, to avoid releases to the workplace atmosphere and in any situation, to control the inhalation of such material by workers to levels that are ALARA; confinement and ventilation shall normally be used.
iv. The design or modification of a facility and the selection of materials shall include features that facilitate operations, maintenance, decontamination, and decommissioning.

6.5 DESIGN OUTPUTS

The outputs of design and development are provided in a form that enables verification against the design and development input and are approved prior to release.

Design and development outputs:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

6.6 PRESSURE SYSTEMS

SNS design for pressure systems follows these rules:

a. Establish safety policies and procedures to ensure pressure systems are designed, fabricated, tested, inspected, maintained, repaired, and operated by trained and qualified personnel in accordance with applicable and sound engineering principles.
b. Ensure that all pressure vessels, boilers, air receivers, and supporting piping systems conform to:
   (1) the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Safety Code;
   (2) the American National Standards Institute/ASME B.31 Piping Code; and/or
   (3) the strictest applicable state and local codes.
c. When national consensus codes are not applicable (because of pressure range, vessel geometry, use of special materials, etc.), implement measures to provide equivalent protection and ensure safety equal to or superior to the intent of the ASME code. Measures

will include the following.

(1) Design drawings, sketches, and calculations are reviewed and approved by an independent design professional. Documented organizational peer review is acceptable.

(2) Qualified personnel are used to perform examinations and inspections of materials, in-process fabrications, non-destructive tests, and acceptance tests.

(3) Documentation, traceability, and accountability are maintained for each unique pressure vessel or system, including descriptions of design, pressure, testing, operation, repair, and maintenance.

6.7 DESIGN AND DEVLOPMENT VALIDATION, VERIFICATION AND REVIEW

Both software and hardware design and development are covered by these requirements.

SNS will verify/validate the adequacy of design products through individuals or groups other than those who performed the work, and verify/validate work before approval and implementation of a design.

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

Design and development validation are performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements,

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews will include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained

6.8 CONTROL OF CHANGES

Software design and hardware design are both covered by these requirements.

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes will include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions are maintained.

7. PERFORMANCE/CRITERION 7—PROCUREMENT

The procurement process described in this section is implemented by procedure SNS-QA-P070, “Procurement.”

Procurement controls are implemented to ensure that purchased items and services meet SNS needs and comply with applicable quality requirements.

SNS procurement rules include:

(1) Procure items and services that meet established requirements and perform as specified

(2) Evaluate and select prospective suppliers on the basis of specified criteria

(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

7.1 FLOWDOWN OF DOE REQUIREMENTS

SNS is responsible for flowing down the requirements of the CRD in ref. 1 to subcontractors at any tier to the extent necessary to ensure the contractor's compliance with the requirements and the safe performance of work.

7.2 SUBCONTRACTOR RECORDS

SNS ensures subcontractors generating records will generate them in accordance with established procedures and provide identification of records to be generated, accessibility of records to SNS personnel, a mechanism and funding for records turnover, a method of verification that requirements are met before contract closure, and a method of advising secondary subcontractors of applicable requirements.

7.3 DEVELOPMENT OF SPECIFICATIONS

SNS personnel requesting procurement of items and services are responsible for providing technical, quality, ES&H, and other specifications that adequately describe the item or service being procured so that the supplier can understand what is desired and what will be accepted. Where drawings are used to control the fabrication of parts built to SNS designs, the requirements in this section apply to the drawings.

Development of these specifications (or drawings) may be achieved through the involvement of QA representatives and through established review and approval systems. The following factors should be considered:

- technical performance requirements,
- appropriate standards,
- laws and regulations, and
- acceptance criteria..

7.4 SUPPLIER EVALUATION

Suppliers of quality level 1 or 2 items or services should be evaluated to determine their ability to provide acceptable items and services. The evaluation typically includes reviews by the QA representative.

Previously accepted suppliers should be appropriately monitored to ensure that they continue supplying acceptable items and services. Incoming items will be verified against previously established acceptance criteria.

7.5 SUPPLIER PERFORMANCE

Unacceptable items or services are documented. Records of supplier performance (ACLs, NCRs, and contract-required submittals) are retained where needed for future procurement consideration.

8. PERFORMANCE/CRITERION 8—INSPECTION AND ACCEPTANCE TESTING

The terms “products” or “items” as used here may refer to items or services for use in construction or maintenance of the facility and equipment, as well as those for users or other external entities. The process described in this section is implemented in detail by procedure SNS-QA-P080, “Inspection and Acceptance Testing.” It includes rules for:

(1) Inspecting and testing specified items, services, and processes using established acceptance and performance criteria.

(2) Calibrating and maintaining equipment used for inspections and tests.

The SNS program includes required verification and inspection activities specific to the items and the criteria for their acceptance.

The program includes required testing activities specific to the items and the criteria for their acceptance.

SNS uses suitable methods where applicable, for measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results.

SNS monitors and measures the characteristics of its products to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

8.1 ACCEPTANCE CHECK LISTS (ACL’S)

ACL forms, installation travelers, and the ACL database are the primary tools used to organize this activity. They are generic for use at any stage of work.

8.2 TEST PLANS

Turnover from installation or maintenance to operations is formalized with completion of approved test plans.

SNS also performs the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.

A program for inspection of activities affecting quality is established and executed by SNS to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The program includes required verification and inspection activities specific to the product and the criteria for product acceptance.

SNS performs the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

SNS uses appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

SNS has instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up to date and are available to personnel. Deviation from test and calibration methods is permitted only if the deviation has been documented, technically justified, authorized, and accepted by the client.

8.3 PRESSURE SYSTEMS

(1) Qualified personnel are used to perform examinations and inspections of materials, in-process fabrications, non-destructive tests, and acceptance tests.
(2) Documentation, traceability, and accountability are maintained for each unique pressure vessel or system, including descriptions of design, pressure, testing, operation, repair, and maintenance.

8.4 SUPPLEMENTAL QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR S/CI'S DOE-WIDE SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS

The DOE Office of Environment, Safety and Health operates an S/CI process as a service to DOE and its contractors, and provides for collecting, analyzing, and disseminating S/CI information; notifying Secretarial Officers (SOs) when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and tracking and reporting the status of corrective actions.

NOTE: This service does not relieve the contractor from complying with the requirements defined in the o 414.1C CRD (ref. 1).

Suspect/Counterfeit Items (S/CI).

An item is suspect when visual inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

(1) defects resulting from inadequate design or production quality control;
(2) damage during shipping, handling, or storage;
(3) improper installation; deterioration during service;
(4) degradation during removal;
(5) failure resulting from aging or misapplication; or
(6) other controllable causes.

An S/CI prevention process must be developed and implemented as a part of the contractor's QAP and must be commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying, analyzing, and removing S/CIs, and preventing them from being supplied to DOE/NNSA and its contractors. The QAP must address the following elements for S/CI prevention.

1) Preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls.
2) Training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).
3) Identifying and disposing of S/CIs on site.
4) Restricting S/CI use to only those items that have been found acceptable through engineering analysis and formal disposition process.
5) Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources. S/CI information sources include the following.

(a) Government-Industry Data Exchange Program (www.gidep.org);
(b) Institute of Nuclear Power Operators (www.inpo.org);
(c) DOE Occurrence Reporting and Processing System; and
(d) DOE S/CI website (http://tis.eh.doe.gov/paa/sci/).

6) Identifying the management point of contact responsible for these activities to ensure that the DOE Office of Environment, Safety and Health has a viable recipient for S/CI information notices.

Work Process Controls.

Work processes must be developed and implemented using available S/CI information, and must include the following elements.

1) Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment.
2) Procurement processes that prevent introduction of S/CIs by—
   (a) identifying technical and QA requirements in procurement specifications;
   (b) accepting only those items that comply with the procurement specifications consensus standards, and commonly accepted industry practices; and
   (c) inspecting inventory and storage areas to identify, control, and disposition S/CIs.
3) Inspection, identification, evaluation, and disposition of S/CIs installed in all Safety applications[1] and other applications that create potential hazards. Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers. This term includes safety systems in nuclear facilities (see 10 CFR 830.2).
4) Engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards. The evaluations must consider potential risks to the public and worker and cost/benefit impact, and include a schedule for replacement (if required).
5) Ensuring that S/CIs identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.
6) Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.
7) Testing procured or installed S/CIs as necessary using approved engineering test methods.
8) Reporting S/CIs to responsible DOE/NNSA line management offices; the Office of Environment, Safety and Health; and the IG. [DOE O 231.1A, *Environment, Safety, and Health Reporting*, dated 8-19-03, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse*, dated 3-22-01.]
9) Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention.

9. ASSESSMENT/CRITERION 9—MANAGEMENT ASSESSMENT

The management assessment process described in this section is implemented by procedure SNS-QA-P090, “Management Assessment.”

SNS ensures that managers assess their management processes and identify and correct problems that hinder SNS from achieving its objectives. Also,

a) An internal safety review system must be established and maintained to periodically assess and document the condition of the facility, equipment, and engineered safety systems.

b) Appropriateness and implementation of procedures, administrative controls, and personnel training and qualifications must be periodically reviewed and documented by the internal safety review system.

SNS management at all levels shall regularly evaluate achievement relative to performance requirements and shall appropriately validate or update performance requirements and expectations to ensure quality. The management assessment process shall periodically include an evaluation of the organization's products and processes to determine whether the project's missions are being fulfilled. The results of management assessments, which focus on means to improving the quality of work performed, shall be reported to the appropriate responsible line or project management level.

When performance does not meet established standards, management shall, with the assistance of others with appropriate expertise, determine the cause and initiate corrective action. QA representatives may assist, lead, or facilitate cause investigations.

For research activities, management assessments shall include the review and evaluation of research results by managers or peer groups (e.g., standing or ad hoc panels and committees) directed by management.

9.1 MANAGEMENT REVIEW

The ALD for SNS and the division-level managers review the SNS quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews will be maintained.

Review input

The input to management review includes information on

b. results of audits,
c. customer feedback,
d. process performance and product conformity,
e. status of preventive and corrective actions,
f. follow-up actions from previous management reviews,
g. changes that could affect the quality management system, and
h. recommendations for improvement.

Review output

The output from the management review includes any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

10. ASSESSMENT/CRITERION 10—INDEPENDENT ASSESSMENT

The independent assessment process described in this section is implemented by procedure SNS-QA-P100, "Independent Assessment."

It contains rules including:

(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

(2) Establish sufficient authority and freedom from line management for independent assessment teams

(3) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

10.1 ACCELERATOR READINESS REVIEWS (ARR'S)

ARRs must be performed before approval for commissioning and routine operation and as

directed by the DOE cognizant Secretarial Officer/NNSA Deputy Administrator or a DOE/NNSA field manager.

To ensure mitigation of hazards will be effective, a series of formal reviews and assessments will demonstrate readiness to proceed to each level of commissioning and operation. ES&H programs, including documentation, staffing, and training, will be evaluated in these reviews and assessments prior to actual conduct of work. This system of independent reviews is used for the accelerator and target, and major neutron instruments.

In accordance with the principles of ISM, the SNS line management is responsible for safety at the SNS facilities. As explained in refs. 14 and 15, the SNS organization includes ES&H management and staff to provide direction and support to the line management. A system of internal review committees provides opportunity and process for multidisciplinary peer review of safety questions in the design and operation of the facility.

SNS QA management will plan and conduct independent assessments to assist line managers in identifying opportunities for quality improvement and to ensure compliance with specified requirements. Independent assessments of the SNS Project can be sponsor driven or be requested by SNS management. Independent assessments typically focus on quality or ES&H management systems, self-assessment programs, or other organizational functions identified by management.

Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed. A qualified lead assessor (auditor) is required, and the team may include other subject-matter experts to evaluate the adequacy and effectiveness of activities if they are not responsible for the work being assessed.

Additionally, three important independent boards and committees have been chartered to advise ORNL and SNS management: the SNS Advisory Board, the Experimental Facilities Advisory Committee, and the Accelerator Systems Advisory Committee.

The SNS Advisory Board will identify and bring to the attention of the UT-Battelle Board of Governors any issues whose resolution is critical to the technical success of the project and to meeting project performance, cost and schedule goals. It receives inputs from the other two committees.

The Experimental Facilities Advisory Committee provides advice to SNS management concerning the experimental facilities, comprising the neutron source system and instrumentation.

Similarly, the Accelerator Systems Advisory Committee is charged to provide an assessment of the physics and technical progress on the accelerator.

DOE also performs external assessments that provide an objective view of performance and as a result contribute to the independent assessment process. Since such assessments are not under the control of SNS, they are not necessarily considered as being part of the independent assessment criterion. However, SNS management considers external assessment results and schedules in determining the scope of its planned management and independent assessments.